IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
LAREDO DIVISION

UNITED STATES OF AMERICA,	§	CRIMINAL NO. L-13-cr-1406
	§	18 U.S.C. § 2
	§	21 U.S.C. § 331(a)
EDUARDO MIRANDA	§	21 U.S.C. § 333(a)

AMENDED CRIMINAL INFORMATION

THE UNITED STATES CHARGES THAT:

INTRODUCTION

At all times material to this Information:

1. Defendant EDUARDO MIRANDA was a resident of Laredo, Texas.

2. Defendant EDUARDO MIRANDA was a physician licensed to practice medicine in the State of Texas and maintained a medical practice at 2344 Laguna Del Mar Court, Suite 104, Laredo, Texas.

3. Defendant EDUARDO MIRANDA was an oncologist who specialized in providing medical services to patients who suffered from cancer.

4. Defendant EDUARDO MIRANDA ordered and received prescription drugs for the treatment of cancer from foreign sources which had not been approved by the United States Food and Drug Administration "FDA" for distribution and use in the United States.

5. Defendant EDUARDO MIRANDA provided and administered FDA-unapproved oncology drugs that had been obtained from foreign sources to patients for the treatment of cancer without their knowledge.

6. Defendant EDUARDO MIRANDA billed the Medicare and Medicaid health care benefit programs and private insurance companies for providing FDA-unapproved prescription drugs to patients.

7. Defendant EDUARDO MIRANDA billed health care benefit programs approximately $3.4 million and was paid more than $1 million for providing prescription drugs to patients that had not been approved by the FDA for the treatment of human diseases.

8. Quality Specialty Products ("QSP") was a business entity located in Winnipeg, Canada, that shipped pharmaceutical drugs products into the United States which had not been approved by the FDA for distribution and use for the treatment of human diseases.

FDA STATUTES AND REGULATIONS

9. The United States Food and Drug Administration ("FDA") was the federal agency charged with the responsibility of protecting the health and safety of the American public by, enforcing the Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 *et. seq.* ("FDCA"). FDA's responsibilities under the FDCA included regulating the manufacture, labeling, the distribution of all drugs and drug components shipped or received in interstate or foreign commerce, including the wholesale distribution of prescription drugs. To meet those responsibilities, the FDA enforced statutes which required that drugs bore labels and labeling that enabled health care providers and consumer to use them in a safe manner and that drugs were listed by and manufactured in facilities registered with the Secretary of the United States Department of Health and Human Services. 21 U.S.C. §§ 352(f), 352(o) and 360(c).

10. The FDCA prohibits the introduction or delivery for introduction into interstate

commerce, or the causing thereof, of any drug that is adulterated or misbranded. 21 U.S.C. §331(a).

11. Under the FDCA, a drug is deemed misbranded unless its labeling bears adequate directions for use. 21 U.S.C. §352(f)(1).

12. Under the FDCA, the term "label" means a display of written, printed or graphic matter upon the immediate container of any article. 21 U.S.C. §321(k). The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article. 21 U.S.C. §321(m).

13. Under the FDCA, anyone manufacturing, preparing, compounding, or processing prescription drugs for sale and use in the United States must annually register with the FDA as a drug establishment and provide a list of the drugs which are being manufactured for commercial distribution. 21 U.S.C. §§360(a)(1),360(b),360(i) and 360(j). The FDCA's registration requirement applies to both businesses located within the United States and drug establishment located outside of the United States. 21 U.S.C. §§360(b), 360(i) Any drug establishment located within or outside of the United States may be inspected by the FDA for officials of foreign governments that act cooperatively with FDA. 21 U.S.C. §360(h), 360(i)(3).

Prescription Drugs

14. Under the FDCA, drug includes: articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or articles intended to affect the structure of any function of the body of man. 21 U.S.C. § 321(g)(1)(B) and (C).

15. Under the FDCA, a drug was deemed to be a prescription drug if, because of its

toxicity and other potential harmful effects, it was not safe for use except under the supervision of a practitioner licensed by law to administer the drug. A drug was also deemed to be a prescription drug if a new drug application approved by the FDA limited the drug to use under the professional supervision of a practitioner licensed by law to administer the drug. 21 U.S.C. §§ 353(b)(1), 355.

16. The drugs listed below, using the names under which the drugs are marketed in the United States, are used primarily to treat individuals with cancer, and often infused into cancer patients intravenously, meaning the purity and efficacy of these prescription drugs is very important for patients. All of these drugs were prescription drugs pursuant to 21 U.S.C. §353(b)(1) because of their toxicity or other potentiality for harmful effect, and could lawfully be dispensed only upon the prescription of a practitioner licensed by law to administer such drugs: (1) Kytril; (2) Taxotere; (3) Zometa; (4) Eloxatin; and (5) Gemzar.

Misbranding of Prescription Drugs

17. Under the authority of the FDCA, 21 U.S.C.§§ 301-399, a drug is misbranded under the FDCA unless the labeling bore adequate directions for use. 21 U.S.C. §352(f). "Adequate directions for use" means directions under which a layman can use a drug safely and for the purposes for which it is intended. 21 C.F.R. §201.5. All words, statements and other information required to appear on drug labeling by the FDCA must be in English language, unless the drug is solely distributed in Puerto Rico or a United States territory. 21 C.F.R. §201.15(c)(1).

18. A drug is also misbranded if it was manufactured, prepared, propagated,

compounded, processed in any establishment in any state not duly registered with FDA. 21 U.S.C. §352(o). Finally, any drug is misbranded if it came from a domestic or foreign drug establishment and that drug was not annually listed with the FDA by the establishment as one of the drugs which was being manufactured, or commercial distribution in the United States at that drug establishment. 21 U.S.C. §§352(o), 360(j).

COUNT ONE
(Misbranded Drugs)
(21 U.S.C. § 331(a))

19. On or about October 1, 2007 and continuing through January 28, 2009, in the Southern District of Texas and elsewhere within the jurisdiction of the Court, the defendant,

EDUARDO MIRANDA,

aided and abetted by others known and unknown to the United States Attorney, caused the introduction and delivery for introduction into interstate commerce of drug products that were misbranded in that the package containing the drugs: (1) did not bear adequate directions for use; (2) the drug products were manufactured, prepared, propagated, compounded, processed in any establishment in any state not duly registered with FDA; and (3) the drug products came from a domestic or foreign drug establishment and that drug products were not annually listed with the FDA by the establishment as one of the drugs which was being manufactured for commercial distribution in the United States at that drug establishment.

In violation of Title 18, United States Code, Section 2 and Title 21, United States Code, Sections 331(a), 352(f), 352(o) and 333(a)(1).

KENNETH MAGIDSON
UNITED STATES ATTORNEY

By: _____
SONAH LEE
Assistant United States Attorney
Southern District of Texas

_____
RAUL GUERRA
Assistant United States Attorney
Southern District of Texas

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CRIMINAL DOCKET

LAREDO **DIVISION**

NO. 5:13cr1406

FILE: 2009R02803
INFORMATION

Filed: 12/19/13

Judge: JSH

ATTORNEYS:

UNITED STATES OF AMERICA

KENNETH MAGIDSON, USA
SONAH LEE, AUSA
RAUL GUERRA, AUSA

VS.

EDUARDO MIRANDA

CHARGE: Ct. 1: Introducing Misbranded Drugs into Interstate Commerce
[21 USC §§ 331(a), 352(f) and 18 USC § 2]

TOTAL COUNTS: 1

PENALTY: Ct.1: Not more than ONE YEAR and/or $100,000 and $25 Special Assessment,
Not more than One Year Term of Supervised Release

In Jail:

On Bond:

Name and Address of Surety:

No Arrest: